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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,658	07/22/2002	Alvin Berger	112843-044	6858

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EXAMINER	
EBRAHIM, NABILA G	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,658	BERGER ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/19/05 has been entered.

Prosecution

Prosecution of the current application has been transferred from Examiner Berko Retford to Examiner Nabila Ebrahim.

Status of the claims

Claims 1, 3-25 are pending in the application.

Claim 2 was cancelled.

Rejection Withdrawal

In view of the amendments shown in claims 3, and 4, the rejection under 35 U.S.C § 112, second paragraph has been withdrawn.

In view of the arguments filed on 10/17/05 the rejection of claims 1, 5, 16, 22 and 25 under 35 U.S.C. 102(b) as being anticipated by Stordy et al (WO 96/37200) is withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Because the specification does not reasonably provide enablement for a method of preventing an anandamide mediated ailment selected from the group consisting of hypertension, glaucoma, insomnia, pain, inflammation, migraine headaches, loss of appetite, nausea, cramps, diarrhea, gut upsets, intestinal motility disturbances, asthma, nervousness, aggressive behavior, excessive timidity, inability to sleep, catalepsy, low mood, depression, spasms, poor motor control, tics, excessive stress, spasticity, multiple sclerosis, and vocalization, poor language acquisition, skin inflammation, and excess nociception. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in

the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

1) The breadth of claims: claim 17 is directed to a method of preventing an anandamide mediated ailment selected from the group consisting of hypertension, glaucoma, insomnia, pain, inflammation, migraine headaches, loss of appetite, nausea, cramps, diarrhea, gut upsets, intestinal motility disturbances, asthma, nervousness, aggressive behavior, excessive timidity, inability to sleep, catalepsy, low mood, depression, spasms, poor motor control, tics, excessive stress, spasticity, multiple sclerosis, and vocalization, poor language acquisition, skin inflammation, and excess nociception. This is a very broad claim, one that is not supported by the instant specification.

2) The nature of the invention: The invention is drawn to a composition for oral administration comprising comprising a naturally occurring precursor that is a compound having anandamide activity for use as a medicament. The rejected claim, however, is drawn to a method of preventing an anandamide-mediated ailment selected from the group consisting of hypertension, glaucoma, ..etc.

3) The state of the prior art: The state of the art is very high in terms of compositions comprising anandamide containing compound for the treatment of for example, psychiatric problems, pain, migraine headaches, inflammation, glaucoma, hypertension, and vocalization problems. Although a number of publications describe methods of treating different ailments using compounds comprising anandamides (US

5, 618, 955, US 20040127518), there is no evidence in the prior art that the instant composition would prevent all or any of the listed ailments.

4) The amount of direction provided by the inventor: There is nothing in the specification that would indicate that the current invention prevents all the listed health problems. The prevention of all these ailments is considered a very broad claim. With respect to the methods recited in the instant application, there is a substantial gap between treatment and prevention. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

5) Predictability of the art: The prior does not teach a method of preventing hypertension, glaucoma, insomnia, pain, inflammation, migraine headaches, loss of appetite, nausea, cramps, diarrhea, gut upsets, intestinal motility disturbances, asthma, nervousness, aggressive behavior, excessive timidity, inability to sleep, catalepsy, low mood, depression, spasms, poor motor control, tics, excessive stress, spasticity, multiple sclerosis, and vocalization, poor language acquisition, skin inflammation, and excess nociception.

6) The presence or absence of working examples: Applicant describes no examples in the instant specification, none of which teach a method of preventing of any ailment. Overall, applicant fails to provide examples indicating that the instant composition can prevent the health problems listed in claim 17 by an oral composition comprising anandamides. Therefore, the practitioner would turn to trial and error experimentation to make/use of the instant compositions for preventing health problems, without guidance from the specification or the prior art.

7) The quantity of experimentation: In the instant case, there is a substantial gap between treatment and prevention. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap. In order to utilize the composition as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. An undetermined number of experimental factors utilizing a system for preventing health problems recited in claim 17 by an oral composition comprising anandamide. The factors are not sufficiently discussed in the specification to provide guidance to utilize the invention as claimed.

8) The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "and having a moiety selected from the group consisting of methylated-, branched, ..etc."; the term methylated- does not represent a moiety, the term methylated- is vague and indefinite because it refers to a chemical derivation but it does not specify atoms that are modified by addition of a methyl group that's why the term methylated- does not refer to a chemical moiety.

2. Claims 15, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. The claims recite many health problems that are not specified and too broad to be identified. For example "gut upsets", "intestinal motility" are unclear terms, they do not demonstrate what they include or exclude. For example intussusception, paralytic ileus, and intestinal polyps, are these problems considered as "gut upsets" or "intestinal motility" problems?

In addition, the term "aggressive behaviors" is an indefinite term, since it does not demonstrate what does it include or exclude. Does the term mean people who have tendency to have physical or verbal confrontation or does it include psychopaths and/or criminals? The same rejection includes the following terms: "excessive timidity", "poor motor control", and "vocalization". Applicant is required to determine the exact disorders included that can be treated by using the nutritional preparations recited in the claims.

3. Claims 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite methods of manufacturing, treating, and preventing disorders, which include insomnia and inability to sleep. The two terms have the same meaning and are considered as repetition. Insomnia is defined as inability to sleep or to remain asleep throughout the night.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1, 2 and 5 under 35 U.S.C. 102(b) as being anticipated by Mechoulam et al (US 5, 618, 955) is maintained. Mechoulam et al (Patent '955) teaches a composition comprising arachidonyletanolamide (anandamide) and derivatives (abstract, col. 4, lines 1-15, col. 13, lines 60-65, col. 7, lines 65 and col. 10, lines 10-15). The claims are directed toward composition for oral administration. As in applicant's claims, Mechoulam et al teaches dosage forms of the composition for oral administration (col. 5, lines 20).

Claims 1, 2 and 5 are anticipated by Patent '955.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1, and 3-25 as unpatentable under 35 U.S.C. 103(a) over Mechoulam et al (US 5, 618, 955) in view of the combination of Stordy et al (WO 96/37200, Makriyannis et al (US 5, 874, 459) and Kyle et al (WO 94/28913) is maintained.

Mechoulam (Patent '955) disclose a pharmaceutical composition comprising arachidonyletanolamide (anandamide) and derivatives (see abstract, co13, lines 60-65, col. 7, lines 65 and col. 10, lines 10-15. Mechoulam discloses the biological activity of anandamide such as antiemetic and antiglucoma activity and other ailments (abstract; col. 3, lines 35-50 and col. 4, lines 30-60). Mechoulam also teaches compounds of active unsaturated achylethanolamides isolated and/or prepared like cis-4,7,10,13,16,19-docosahexaenylethanolamide (see col. 7, and 8).

Mechoulam does not teach a method of producing a nutritional or therapeutic composition comprising docosahexanoate or anandamide from naturally occurring source and does not teach a method of treating a patient with the composition to alleviate an ailment.

Stordy et al (patent '200) disclose a method of treating dyslexia using DHA (abstract, page 1, and 2) according to Stordy, DHA is particularly important in the function of

retinal rods and that DHA significantly improves dark adaptation, reading ability and behaviors in children (page 2, and 3); however, Stordy provides no indication of whether the compound reacts with the CB receptors.

A skilled man in the art would be motivated to include DHA to a compound having a anandamide activity since Stordy disclosed that docosahexaenoic (DHA) is a major constituent of the retina, of nerve tissue and of the brain. It would be expected to advance Mechoulam, which was known to be treating diseases like glaucoma, spasticity, multiple sclerosis, and migraine (see Mechoulam's abstract)

Makriyannis et al (Patent '459) disclose novel inhibitors of anandamide amidase, said inhibitors react with CB1 and CB2 receptors (abstract, col. 2, lines 15-20 and col. 7, lines 45-50). Patent '459 discloses that a therapeutically effective amount of the anandamide amidase inhibitors also an amount that results in a sufficiently high level of anandamide in an individual to cause physiological effects that result in stimulation of the CB receptors, thus stimulating other biological effects such as decreased nausea resulting from chemotherapy, sedation and increased appetite as well as relieving intra-ocular pressure in glaucoma patients (col. 5, lines 60- 65, continuing to col. 6, lines 1-5).

Kyle et al (WO '913) disclose the outstanding limitation in that patent '913 disclose a method of treating patients suffering from neuro-degenerative ailments associated with DHA or arachidonate (ARA) deficiency (abstract and page 6 lines 1-30, continuing to page % lines 1-5). More importantly, Patent (31 7 discloses preparation of DHA and ARA oils from natural sources and extracting such compounds from the biomass of cultivated microorganisms (page 8, lines 25 and page 21, lines 5-10).

According to Kyle et al, the administration of DHA and ARA offer significant advantage over merely obtaining linolenic or linoleic acid from standard foods (page 25, line 32).

One of ordinary skill would have been motivated to prepare a composition comprising DHA and ARA for administration to patients as disclosed by the prior art cited. One of ordinary skill would expect to alleviate symptoms of neuro-degenerative diseases in patients because patent '459 has disclosed that effective amounts of long chain fatty acids that interact with CB receptors also intraocular pressure in glaucoma, stimulate analgesia and elicit anti-emetic activity by reacting with CB 1 and CB2 receptors (Patent '459, col. 5, lines 60-65, continuing to col. 6, lines 1- 5). Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in t he art at the time the invention was made.

Response to Arguments

6. Applicant's arguments filed 10/17/05 have been fully considered but they are not persuasive.

applicant argues that:

Mechoulam is directed to the use of final synthesis or end products, while the current application is directed to utilizing the intermediates or precursors for forming these polyunsaturated fatty acid amides.

In response to this argument, the examiner would like to explain that Mechoulam discloses the same formula of anandamide, and since the instant claimed invention is a composition, the mechanism of action of the claimed composition should not been given patentable weight, because the prior art compositions would be at least capable

inherently of achieving the same mechanism. For example, if you administer a tablet of aspirin to a patient, it will go through different mechanisms to achieve 3 expected pharmacological effects as an antipyretic, analgesic and anti-inflammatory.

Applicant also argues that Mechoulam fails to disclose or suggest any of the compounds in a nutritional composition.

In response to this argument, the examiner always examines the claim as written by the applicant. Claim 14 recites a nutritional or therapeutic composition and since Mechoulam discloses his composition to be a therapeutic oral administration (col. 5, line 2). It is not an obligation to search the prior art for a nutritional comprising the recited compounds.

Applicant challenges Stordy and Kyle claiming that they used non-modified polyunsaturated acids like DHA or ARA. And Makriyannis does fails to disclose or suggest a composition for oral administration comprising a naturally occurring precursor that is metabolized to a compound having anandamide activity.

In response, it is the examiner's position to assert that a claim rejections - 35 USC § 103 does not necessitate all the elements present in the recited claims to be in one prior art, however, It requires a combination, which is provided by any of the three arts combined with Mechoulam.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim 3/13/06

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER